

WE CLAIM AS OUR INVENTION:

1. A compliant and substantially non-elastic pericardial reinforcement comprising a compliant and substantially non-elastic member having an interior surface for placement adjacent an epicardium, the interior surface tending to inhibit adhesions with the epicardium and having an exterior surface for attachment to the interior of a pericardium.

2. The pericardial reinforcement of claim 1 where the interior surface comprises at least one material that does not substantially permit ingrowth with said epicardium.

3. The pericardial reinforcement of claim 1 where the interior surface comprises at least one material that resists ingrowth with the epicardium.

4. The pericardial reinforcement of claim 1 where the compliant member is conformable in shape to at least a portion of the epicardium.

5. The pericardial reinforcement of claim 1 where the interior surface comprises a lubricious material.

6. The pericardial reinforcement of claim 1 where the interior surface comprises a lubricious polymeric material.

7. The pericardial reinforcement of claim 6 where the interior surface polymeric material comprises a fluorocarbon polymer.

8. The pericardial reinforcement of claim 7 where the fluorocarbon polymer is selected from the group consisting of polytetrafluoroethylene, ethylene-chlorofluoroethylene, fluorinated ethylene propylene, polychlorotrifluoroethylene, polyvinylfluoride, and polyvinylidenefluoride.

9. The pericardial reinforcement of claim 7 where the fluorocarbon polymer comprises ePTFE.

10. The pericardial reinforcement of claim 7 where the fluorocarbon polymer comprises ePTFE having internodal spacing less than about 40 microns.

11. The pericardial reinforcement of claim 6 where the polymer material comprises a member selected from the group consisting of LLDPE, LDPE, HDPE, polypropylene, polyamides, their mixtures and co-polymers.

12. The pericardial reinforcement of claim 1 where the exterior surface comprises a material for ingrowth into the pericardium.

13. The pericardial reinforcement of claim 1 where the exterior surface comprises a material allowing attachment to the pericardium.

14. The pericardial reinforcement of claim 1 where the exterior surface comprises a material for adherence with the pericardium.

15. The pericardial reinforcement of claim 1 where the exterior surface further comprises a material promoting endothelialization.

16. The pericardial reinforcement of claim 15 where the material promoting endothelialization comprises an effective hyalonurate salt.

17. The pericardial reinforcement of claim 15 where the material promoting endothelialization comprises an effective amount of an angiogenic material.

18. The pericardial reinforcement of claim 1 where the exterior surface comprises a material enhancing ingrowth with the pericardium.

19. The pericardial reinforcement of claim 7 where the exterior surface material comprises a polymeric material.

20. The pericardial reinforcement of claim 19 where the polymeric material is selected from the group consisting of polyethylene terephthalate, polyglycolic acid, polylactic acid, reconstituted collagen, poly-*p*-dioxanone, poly(glycolide-lactide) copolymer, poly(glycolide-trimethylene carbonate) copolymer, poly(glycolide- ϵ -caprolactone) copolymer, glycolide-trimethylene carbonate triblock copolymer, their block and random copolymers, mixtures, and alloys.

21. The pericardial reinforcement of claim 19 where the polymeric material comprises ePTFE.

22. The pericardial reinforcement of claim 21 where the ePTFE has internodal spacing greater than about 60 microns.

23. The pericardial reinforcement of claim 1 where the exterior surface material comprises a woven or non-woven polymeric material.

24. The pericardial reinforcement of claim 23 where the exterior surface material comprises a woven polymeric material.

25. The pericardial reinforcement of claim 23 where the exterior surface material comprises a non-woven polymeric material.

26. The pericardial reinforcement of claim 1 further comprising at least one mechanical linkage configured to attach the exterior surface to the pericardium.

27. The pericardial reinforcement of claim 26 where the at least one mechanical linkage comprises at least one suture.

28. The pericardial reinforcement of claim 26 where the at least one mechanical linkage comprises at least one staple.

29. The pericardial reinforcement of claim 26 where the at least one mechanical linkage comprises a material selected from the group consisting of adhesives and glues.

30. The pericardial reinforcement of claim 29 where the adhesives and glues are selected from the group consisting of acrylate-based glues, cyanoacrylate-based glues, and fibrin-based glues.

31. The pericardial reinforcement of claim 30 where the at least one mechanical linkage comprises an acrylate-based glue.

32. The pericardial reinforcement of claim 30 where the at least one mechanical linkage comprises a cyanoacrylate-based glue.

33. The pericardial reinforcement of claim 30 where the at least one mechanical linkage comprises a fibrin-based glue.

34. The pericardial reinforcement of claim 1 where the exterior surface is textured for ingrowth into the pericardium.

35. The pericardial reinforcement of claim 1 where the compliant and substantially non-elastic member comprises an inner member and an outer member.

36. The pericardial reinforcement of claim 35 where at least one of the inner member and the outer member comprises a woven fabric.

37. The pericardial reinforcement of claim 35 where at least one of the inner member and the outer member comprises a non-woven fabric.

38. The pericardial reinforcement of claim 35 where the inner member and the outer member comprise separate layers of woven or non-woven fabric.

39. The pericardial reinforcement of claim 35 where the compliant and substantially non-elastic member comprises an inner member laminated to an outer member.

40. The pericardial reinforcement of claim 35 where at least one of the inner member and the outer member is substantially non-porous.

41. The pericardial reinforcement of claim 35 where at least one of the inner member and the outer member is non-continuous.

42. The pericardial reinforcement of claim 1 further comprising an adjuster adapted for changing a compliant and substantially non-elastic member size after attachment of that member to the interior of the pericardium.

43. The pericardial reinforcement of claim 42 where the adjuster comprises a rotatable roller.

44. The pericardial reinforcement of claim 42 where the adjuster comprises a drawstring.

45. The pericardial reinforcement of claim 1 where the compliant and substantially non-elastic member comprises a band.

46. The pericardial reinforcement of claim 1 where the compliant and substantially non-elastic member comprises a band having an upper end and an apical end and a length extending from the upper end to the apical end and where the length of the band is less than about 1/3 length of a heart to which it is applied.

47. The pericardial reinforcement of claim 46 where the band has a length substantially matching the width of an A-V groove on a heart to which it is applied.

48. The pericardial reinforcement of claim 1 where the compliant and substantially non-elastic member comprises a sack having a closed end.

49. The pericardial reinforcement of claim 48 where the compliant and substantially non-elastic member comprises a sack having a closed end and sized to be positioned only along and less than about 1/3 length of an apical end of heart to which it is applied.

50. The pericardial reinforcement of claim 1 where the compliant and substantially non-elastic member comprises a substantially elongated member having a distal end and a proximal end and configured to be helical upon introduction into the region of the pericardium.

51. The pericardial reinforcement of claim 50 where the compliant and substantially non-elastic member comprises a substantially elongated member having a lumen extending from the proximal end at least partially to the distal end.

52. The pericardial reinforcement of claim 51 where the substantially elongated member includes at least one orifice open to the exterior surface when the device is helically configured in the region of the pericardium.

53. The pericardial reinforcement of claim 52 further comprising a source of glue or adhesive flowable through the at least one orifice, the glue or adhesive suitable for causing adherence between the compliant member and the pericardium.

54. The pericardial reinforcement of claim 53 where the substantially elongated member is expandable upon introduction of the glue or adhesive into the lumen.

55. The pericardial reinforcement of claim 1 where the compliant and substantially non-elastic member comprises an enclosure generally conforming in

shape to at least a portion of an epicardium and the enclosure comprising at least one rib separated by and spaced by webbing.

56. The pericardial reinforcement of claim 55 where the compliant and substantially non-elastic member comprises a band having an upper end and an apical end and a length extending from the upper end to the apical end and having at least two open, generally opposing openings.

57. The pericardial reinforcement of claim 56 where the band has a length less than about 1/3 length of a heart to which it is applied.

58. The pericardial reinforcement of claim 55 where the at least one rib has a flexibility different than the webbing flexibility.

59. The pericardial reinforcement of claim 55 where the at least one rib comprises a generally helical member.

60. The pericardial reinforcement of claim 59 where the generally helical member comprises a ribbon-like member.

61. The pericardial reinforcement of claim 55 where each at least one rib comprises a ribbon-like member.

62. The pericardial reinforcement of claim 61 where each ribbon-like member has a width-thickness ratio greater than about two.

63. The pericardial reinforcement of claim 62 where each ribbon-like member has a width-thickness ratio greater than about seven.

64. The pericardial reinforcement of claim 59 where the generally helical member is inflatable over at least a portion of the enclosure.

65. The pericardial reinforcement of claim 59 where the generally helical member is incrementally inflatable.

66. The pericardial reinforcement of claim 55 where the compliant and substantially non-elastic member comprises an enclosure generally conforming in shape to at least a portion of an pericardium and having an upper end and an apical end and a length extending from the upper end to the apical end and having multiple ribs extending from the upper end to the apical end.

67. The pericardial reinforcement of claim 66 where the multiple ribs are each ribbon-like.

68. The pericardial reinforcement of claim 67 where each ribbon-like member has a cross section with a width-thickness ratio greater than about two.

69. The pericardial reinforcement of claim 68 where each ribbon-like member has a cross section with a width-thickness ratio greater than about seven.

70. The pericardial reinforcement of claim 66 where the multiple ribs each have a round cross section.

71. The pericardial reinforcement of claim 66 where the multiple ribs each have a cross section with a width-thickness ratio of two or less.

72. The pericardial reinforcement of claim 66 where the multiple ribs are each zigzag in shape.

73. The pericardial reinforcement of claim 66 where the multiple zigzag ribs have substantially adjacent points and at least some of the adjacent points are connected.

74. The pericardial reinforcement of claim 55 where at least some of the multiple ribs are joined at the apical end.

75. The pericardial reinforcement of claim 55 where the webbing comprises a woven fabric.

76. The pericardial reinforcement of claim 55 where the webbing comprises a woven, open weave fabric.

77. The pericardial reinforcement of claim 55 where the webbing comprises one or more ribbons extending between at least some of the multiple ribs.

78. The pericardial reinforcement of claim 55 where the webbing comprises one or more fibers extending between at least some of the multiple ribs.

79. The pericardial reinforcement of claim 55 where the webbing comprises an elastic material.

80. The pericardial reinforcement of claim 55 where the webbing comprises a substantially inelastic material.

*not part
of device*

81. The pericardial reinforcement of claim 55 further having a longitudinal opening extending from the upper end towards the apical end and including a plurality of looping members situated on said upper end, said loops deployable over a looping deployment tool.

82. The pericardial reinforcement of claim 55 further including the looping deployment tool, the tool adapted to be removable after placement of the compliant and substantially non-elastic member adjacent said pericardium.

83. The pericardial reinforcement of claim 82 where the looping deployment tool further comprises a connector member for separable connection to an installation member.

84. The pericardial reinforcement of claim 83 where the looping deployment tool further comprises the installation member.

85. The pericardial reinforcement of claim 55 where the compliant and substantially non-elastic member further comprises a connector member for separable connection to an installation member.

86. The pericardial reinforcement of claim 85 where the compliant and substantially non-elastic member further comprises the installation member.

87. A method for reinforcing the pericardium comprising the steps of:

- a.) introducing the pericardial reinforcement of claim 1 below a xiphoid process through a pericardium wall into a pericardial space, and
- b.) positioning the pericardial reinforcement adjacent the pericardium.

88. The method of claim 87 further comprising the steps of puncturing skin beneath the xiphoid process with a needle and an introducer and passing the needle and introducer through the pericardium to the pericardial space.

89. The method of claim 87 further comprising the steps of withdrawing the needle and introducing a guidewire and a cannula through the introducer.

90. The method of claim 87 further comprising the subsequent step of tightening the pericardial reinforcement.

91. A method for reinforcing the pericardium comprising the steps of:
a.) introducing a pericardial reinforcement member through a pericardium wall into a pericardial space, and
b.) positioning the pericardial reinforcement adjacent the pericardium for adhesion to the pericardium.

92. The method of claim 91 further comprising the subsequent step of tightening the pericardial reinforcement member.

101 (part of body)

93. In combination, a pericardium reinforced with the compliant pericardial reinforcement of claim 1.

94. In combination, a pericardium reinforced with the compliant pericardial reinforcement of claim 52.

95. In combination, a pericardium reinforced with the compliant pericardial reinforcement of claim 55.